General

Guideline Title

Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120).

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronization therapy for arrhythmias and heart failure (review of TA95 and TA120). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun. 71 p. (Technology appraisal guidance; no. 314).

Guideline Status

This is the current release of the guideline.

This guideline updates previous versions: National Institute for Health and Clinical Excellence (NICE). Cardiac resynchronisation therapy for the treatment of heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 28 p. (Technology appraisal guidance; no. 120).

National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan 1. 33 p. (Technology Appraisal; no. 95).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Implantable cardioverter defibrillators (ICDs) are recommended as options for:

- Treating people with previous serious ventricular arrhythmia, that is, people who, without a treatable cause:
  - Have survived a cardiac arrest caused by either ventricular tachycardia (VT) or ventricular fibrillation or
  - Have spontaneous sustained VT causing syncope or significant haemodynamic compromise or
  - Have sustained VT without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less but their symptoms are no worse than class III of the New York Heart Association (NYHA) functional classification of heart failure.
- Treating people who:
  - Have a familial cardiac condition with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia or
  - Have undergone surgical repair of congenital heart disease.

ICDs, cardiac resynchronisation therapy (CRT) with defibrillator (CRT-D) or CRT with pacing (CRT-P) are recommended as treatment options for people with heart failure who have left ventricular dysfunction with a LVEF of 35% or less as specified in Table 1.

Table 1. Treatment Options with ICD or CRT for People with Heart Failure Who Have Left Ventricular Dysfunction with an LVEF of 35% or Less (According to NYHA Class, QRS Duration and Presence of LBBB)

	NYHA Class			
QRS Interval	I	II	III	IV
<120 milliseconds	ICD if there is a high risk of sudden cardiac death			ICD and CRT not clinically indicated
120–149 milliseconds without LBBB	ICD	ICD	ICD	CRT-P
120–149 milliseconds with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P
≥150 milliseconds with or without LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P

CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy with defibrillator; CRT-P, cardiac resynchronisation therapy with pacing; ICD, implantable cardioverter-defibrillator; LBBB, left bundle branch block; NYHA, New York Heart Association

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Ventricular arrhythmia
- Heart failure
- Cardiac conditions with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia

Guideline Category

Prevention

Technology Assessment

Treatment

Clinical Specialty

Cardiology

Internal Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To appraise the clinical- and cost-effectiveness of implantable cardioverter defibrillators (ICDs) in the treatment of arrhythmias and biventricular pacing (cardiac resynchronisation) to restore synchronous cardiac contraction in patients with advanced heart failure

Target Population

- People at increased risk of sudden cardiac death as a result of ventricular arrhythmias despite optimal pharmacological treatment
- People with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite optimal pharmacological treatment
- People with both conditions described above

Note: In practice these are not distinct populations and there is considerable overlap between the groups, such that people with heart failure due to left ventricular systolic dysfunction are at risk of sudden cardiac death from ventricular arrhythmia.

Interventions and Practices Considered

1. Implantable cardioverter defibrillators (ICDs)
2. Cardiac resynchronisation therapy (cardiac resynchronisation with pacing [CRT-P] or cardiac resynchronisation with defibrillator [CRT-D])

Major Outcomes Considered

- Clinical effectiveness
  - Mortality (including progressive heart failure mortality, non-heart failure mortality, all-cause mortality and sudden cardiac death)
  - Adverse effects of treatment
  - Health related quality of life (HRQoL)
  - Symptoms and complications related to tachyarrhythmias and/or heart failure
  - Heart failure hospitalisations
  - Change in New York Heart Association (NYHA) class
  - Change in left ventricular ejection fraction (LVEF)
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an

independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre (SHTAC) (see the "Availability of Companion Documents" field).

Identification of Studies

A search strategy was developed, tested and refined by an experienced information scientist. The strategy identified clinical-effectiveness studies of implantable cardioverter defibrillators (ICDs) for arrhythmias and cardiac resynchronisation therapy (CRT) for the treatment of heart failure. Additional search strategies identified studies reporting on the cost-effectiveness of ICDs and CRT, and studies reporting on the epidemiology and natural history of arrhythmias and heart failure. Searches to inform cost-effectiveness modeling were also conducted. Sources of information and search terms are provided in Appendix 3 in the Assessment Report. The most recent search was carried out in November 2012.

The following electronic databases were searched: The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), the Cochrane Central Register of Controlled Trials, CRD (University of York) Database of Abstracts of Reviews of Effectiveness (DARE), the National Health Service Economic Evaluation Database (NHS EED) and the Health Technology Assessment (HTA) database; Medline (Ovid); EMBASE (Ovid); Medline In-Process and Other Non-Indexed Citations (Ovid); Web of Science with Conference Proceedings: Science Citation Index Expanded (SCIE) and Conference Proceedings Citation Index - Science (CPCI) (ISI Web of Knowledge); Biosis Previews (ISI Web of Knowledge); Zetoc (Mimas); NIHR-Clinical Research Network Portfolio; Clinical Trials.gov and Current Controlled Trials. Searches were carried out from database inception to the present for studies in the English language. Searches were limited to randomised controlled trials (RCTs) for the assessment of clinical effectiveness and to full economic evaluations for the assessment of cost effectiveness. Bibliographies of retrieved papers and the manufacturers' submission to NICE were assessed for relevant studies that met the inclusion criteria, and the expert advisory group were contacted to identify additional published and unpublished evidence.

Inclusion and Exclusion Criteria

The inclusion criteria for population, interventions and comparators are summarised below.

Summary of Inclusion Criteria

Population	People at increased risk of sudden cardiac death as a result of ventricular arrhythmias despite OPT	People with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite OPT	People with both conditions described to the left
Interventions	ICD in addition to OPT	CRT-P or CRT-D in addition to OPT	CRT-D in addition to OPT
Comparators	Standard care (OPT without ICD)	CRT-P vs CRT-D Standard care (OPT without CRT)	ICD CRT-P Standard care (OPT alone)

CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy with defibrillator; CRT-P, cardiac resynchronisation therapy with pacing; ICD, implantable cardioverter defibrillator; OPT, optimal pharmacological therapy

When screening studies for inclusion it became apparent that the pharmacological therapy in some of the older studies may not be considered optimal by current standards. After consultation with NICE and clinical experts, it was decided that trials in which the pharmacological therapy in either the intervention or comparator arm was not optimal (i.e., current best practice based on clinical opinion) would be included in the systematic review.

Study Design

- For the systematic review of clinical effectiveness, only RCTs were eligible.
- Studies published as abstracts or conference presentations from 2010 onwards were only included if sufficient details were presented to allow an appraisal of the methodology and the assessment of results to be undertaken.
- Systematic reviews of the clinical-effectiveness of ICDs and CRT were used as a source of references.
- For the systematic review of cost-effectiveness, studies were only included if they reported the results of full economic evaluations (cost-effectiveness analyses [reporting cost per life year gained], cost-utility analyses or cost-benefit analyses).
- For the systematic review of quality of life, primary studies or quality-of-life (QoL) collected as part of a trial using European Quality of Life

Questionnaire – 5 Dimensions (EQ-5D) (not visual analogue scale [VAS]), specified by New York Heart Association (NYHA) class for people with heart failure, were included.
- Non-English language studies were excluded.

Screening Process

Studies were selected for inclusion in the systematic review of clinical effectiveness through a two-stage process using the criteria defined above. The titles and abstracts of studies identified by the search strategy were screened by two reviewers to identify all citations that potentially met the inclusion criteria. Full papers of relevant studies were retrieved and assessed by two independent reviewers using a standardised eligibility form. Full papers or abstracts describing the same study were linked together, with the article reporting key outcomes designated as the primary publication.

Titles and abstracts identified by the search strategies for the systematic reviews of cost-effectiveness and quality of life were assessed for potential eligibility by two health economists using predetermined inclusion criteria. Full papers were assessed for inclusion by two reviewers.

Summary of SHTAC Peer Review of Clinical Effectiveness in the ABHI Joint Submission

A joint report on behalf of Biotronik UK, Boston Scientific, Medtronic UK, Sorin Group and St Jude Medical was submitted by the Association of British Healthcare Industries (ABHI) to NICE. The clinical effectiveness evidence presented in this manufacturers' submission (MS) has been briefly appraised (see Appendix 11 in the Assessment Report). The MS also presented individual patient level data (IPD) network meta-analysis (NMA) and an economic model.

A systematic review of clinical effectiveness was undertaken in the MS. Details of the searches were reported and the search strategies were supplied. Details and results of studies included in the systematic review were tabulated. Risk of bias was assessed, although no narrative discussion of risk of bias was provided. The inclusion criteria for the MS systematic review differed from the NICE scope, and the results were not presented according to the population groups defined in the NICE scope. As a result of this, the MS and SHTAC systematic reviews differ in the evidence included (see Appendix 11 in the Assessment Report).

Number of Source Documents

Clinical Effectiveness

- Searches identified a total of 4556 references after de-duplication, and full texts of 222 references were retrieved after screening titles and abstracts. The number of references excluded at each stage of the systematic review is shown in Figure 3 in the Assessment Report (see the "Availability of Companion Documents" field). Selected references which were retrieved but later excluded are listed in Appendix 5 in the Assessment Report with reasons for exclusion. Papers were often excluded for more than one reason; the most common reason being study design (70 papers), followed by comparator (40 papers) and outcomes (32 papers). Although not formally assessed, the level of agreement between reviewers for screening was considered good.
- Searches identified five relevant trials in progress, a summary of which can be seen in Appendix 6 in the Assessment Report (see the "Availability of Companion Documents" field).
- Twenty-six eligible randomised controlled trials (RCTs) were identified (references listed in Table 6 of the Assessment Report), many of these trials were reported in several publications (a total of 78 papers). Thirteen RCTs were considered to involve people at increased risk of sudden cardiac death as a result of ventricular arrhythmias, four trials were considered to involve people with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony and nine RCTs were considered to involve people with both of these conditions.

Cost-effectiveness

- The searches conducted identified 1410 studies that potentially met the inclusion criteria. From screening titles and abstracts, 1334 publications were excluded and 76 retrieved for full screening. Twenty-two retrieved studies did not meet the inclusion criteria.
- A list of relevant excluded studies can be seen in Appendix 12 in the Assessment Report. Fifty-four papers met the inclusion criteria. Three studies were each reported in two publications. Thus, 51 separate economic evaluations were included in this review. A flow chart of the identification of the included studies is given in Figure 31 in the Assessment Report (see the "Availability of Companion Documents" field).

Health-Related Quality of Life

The search strategy identified 6696 references which after filtering for European Quality of Life Questionnaire – 5 Dimensions (EQ-5D) resulted in

218 papers that were potentially relevant. Titles and abstracts were screened and the full text of 22 papers was retrieved for further inspection. After examining the retrieved papers, six studies met the inclusion criteria. A summary of the selection process and the reasons for exclusion are presented in Figure 32 of the Assessment Report. Most studies were excluded because they did not use the EQ-5D or did not report it in the required format. A list of the excluded studies is shown in Appendix 14 in the Assessment Report (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre (SHTAC) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Data Extraction Process

Data from included studies were extracted by one reviewer using a standardised data extraction form and checked by a second reviewer. At each stage, any disagreements were resolved by discussion, with the involvement of a third reviewer where necessary.

Critical Appraisal

The risk of bias of the clinical-effectiveness studies was assessed according to criteria devised by the Cochrane Collaboration. Criteria were applied by one reviewer and checked by a second reviewer, with differences in opinion resolved by consensus and by consultation with a third reviewer if necessary. Economic evaluations were appraised using criteria based on those recommended by Drummond and colleagues, the requirements of the NICE reference case and the suggested guideline for good practice in decision analytic modelling by Philips and colleagues (see Appendix 4 in the Assessment Report [see the "Availability of Companion Documents" field]). Published studies carried out from the UK National Health Service (NHS) and Personal Social Services (PSS) perspective were examined in more detail.

Method of Data Synthesis

Clinical-effectiveness data were synthesised through a narrative review with tabulation of the results of included studies. Where data were of sufficient quality and homogeneity, meta-analysis of the clinical-effectiveness studies was performed to estimate the risk ratio and 95% confidence intervals for relevant outcomes. The random effects method was used. Meta-analysis was performed by using Cochrane Review Manager 5 (RevMan). Statistical heterogeneity was assessed using Chi^2 and degrees of freedom (df), and I^2 statistic. Where standard deviations were not presented in the published papers, these were calculated from the available statistics (confidence intervals, standard errors or p values). A minority of papers reported median values with 95% confidence intervals; in these cases rather than omitting the trial from a meta-analysis, it was assumed that the data were symmetrical (and so the median would be similar to the mean value) and the median was used directly in the meta-analysis.

The Assessment Report contains reference to confidential information provided as part of the NICE appraisal process. This information has been removed from the report and the results, discussions and conclusions of the report do not include the confidential information. These sections are

clearly marked in the report.

Economic Analysis

Systematic Review of Existing Cost-effectiveness Evidence

The economic analysis comprises:

- A systematic review of the literature on the cost-effectiveness of implantable cardioverter defibrillators (ICDs) for people at risk of sudden cardiac death (SCD) and cardiac resynchronisation therapy (CRT) for people with heart failure
- A systematic review of studies of the health related quality of life (HRQoL) of people at risk of SCD or with heart failure
- A review of the manufacturers' submission to NICE
- An independent economic model and cost-effectiveness evaluation (the SHTAC model).

Given the volume of studies meeting the inclusion criteria, data extraction was undertaken as follows: for studies included in previous assessments, data extraction was derived from these reports and checked against original publications; for newly identified evidence, data extraction was undertaken in the normal manner directly from original publications.

Refer to section 5 in the Assessment Report for further details of the economic analysis (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS

and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions on the Evidence for Cost-effectiveness

Availability and Nature of Evidence

The Committee presented cost-effectiveness results for each of the 3 populations outlined in the scope, whereas the manufacturers modelled the individual patient data for 12,638 patients, splitting them into subgroups according to New York Heart Association (NYHA) class, QRS duration, left bundle branch block (LBBB) status and aetiology of heart disease, and reported cost-effectiveness results for each subgroup.

The Committee noted that the approach taken by the manufacturers allows consideration of population groups based on clinical characteristics that are considered important by clinicians in making decisions about device implantation.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee agreed that the duration of constant mortality benefit of 7.5 years was too optimistic because average duration across the trials was 2.54 years. The Committee noted the discrepancy between the modelling of device effectiveness in terms of all-cause mortality and health-related quality of life, in that a constant health-related quality of life benefit was applied for 5 years before tapering.

The Committee noted that the base-case incremental cost-effectiveness ratios (ICERs) were not particularly sensitive to alterations in most cost parameters, including counselling costs. The Committee was concerned that the combined effect of uncertainty had not been explored in a probabilistic sensitivity analysis and concluded that the absence of probabilistic sensitivity analyses made it more difficult to allow for uncertainty when reaching decisions about the cost-effectiveness of the technologies.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values

The manufacturers' model assumed that the health-related quality of life benefit from a device would be maintained for 5 years and thereafter would decrease in a linear manner so that there would be no additional benefit after 10 years.

Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

No.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

The base case deterministic results were presented for 20 subgroups defined by NYHA class, QRS duration and LBBB status, highlighting the most cost-effective treatment strategy at a maximum acceptable ICER of £30,000, £25,000 and £20,000 per quality-adjusted life-year (QALY) gained for each subgroup.

What Are the Key Drivers of Cost-effectiveness?

The manufacturers' base-case ICERs for the devices were most sensitive to changes to the assumptions regarding the magnitude of treatment effect on mortality, duration of constant effect and the duration for which the tapering effect was applied.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

The Committee discussed the results of the manufacturers' analyses for 20 subgroups after combining the ischaemic and non-ischaemic subgroups, based on its preferred assumption of constant mortality benefit being maintained for 5 years followed by tapering up to 20 years.

The most likely ICERs for the Committee's preferred assumptions are presented in Table 2 in the original guideline document, in the evidence section. The most plausible ICERs for the respective recommended devices in the subgroups were between £11,000 and £31,000 per QALY

gained.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the Association of British Healthcare Industries on behalf of the 5 device manufacturers relevant to this appraisal and a review of this submission by the Evidence Review Group (ERG) as well as a systematic review by the ERG.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy (CRT) for arrhythmias and heart failure

Potential Harms

- Adverse events from implantable devices are mostly related to implantation-related complications and include coronary vein dissection, coronary vein perforation, lead dislodgement, infection and death. Patients with defibrillator devices (implantable cardioverter defibrillator [ICD] and cardiac resynchronisation therapy with a defibrillator [CRT-D]) who experience defibrillator shocks may have adverse psychological symptoms (notably anxiety).
- The most frequently reported adverse events in randomised controlled trials with ICDs included defibrillation discharges caused by supraventricular tachycardia or sinus tachycardia (19%, DEBUT); T-wave oversensing (8%, DEBUT); device-related discomfort (7.6%, CIDS); ICDs permanently or temporarily explanted because of infection, heart transplantation or patient preference (5%, CIDS); device dysfunction (5%, CASH); pocket erosion requiring removal of ICD (3%, DEBUT); dislodgement or migration of system leads (3%, CASH); ICD dislodgement/fracture (2.4%, CIDS); bleeding requiring reoperation or transfusion (1.2%, AVID); and unsuccessful first attempt at ICD implantation without thoracotomy (1.0%, AVID).

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has increased risk of ventricular arrhythmias and/or heart failure and the doctor responsible for their care thinks that implantable cardioverter therapy or cardiac resynchronisation therapy is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed tools (see also the "Availability of Companion Documents" field) to help organisations put this guidance into practice (listed below).
    - Costing template and report to estimate the national and local savings and costs associated with implementation
    - A costing statement explaining the resource impact of this guidance
    - Audit support for monitoring local practice

Implementation Tools

Audit Criteria/Indicators

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronization therapy for arrhythmias and heart failure (review of TA95 and TA120). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun. 71 p. (Technology appraisal guidance; no. 314).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2000 Sep (revised 2014 Jun)

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Dr Amanda Adler (*Chair*), Consultant Physician, Addenbrooke's Hospital; Professor Ken Stein (*Vice Chair*), Professor of Public Health, University of Exeter Medical School; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Professor John Cairns, Professor of Health Economics Public Health and Policy, London School of Hygiene and Tropical Medicine; Matthew Campbell-Hill, Lay Member; Dr Lisa Cooper, Echocardiographer, Stockport NHS Foundation Trust; Dr Maria Dyban, General Practitioner; Professor Fergus Gleeson, Consultant Radiologist, Churchill Hospital, Oxford; Robert Hinchliffe, HEFCE Clinical Senior Lecturer in Vascular Surgery and Honorary Consultant Vascular Surgeon, St George's Vascular Institute; Dr Neil Iosson, General Practitioner; Anne Joshua, Associate Director of Pharmacy, NHS Direct; Dr Rebecca Kearney, Clinical Lecturer, University of Warwick; Terence Lewis, Lay Member; Dr Miriam McCarthy, Consultant, Public Health, Public Health Agency; Professor Ruairidh Milne, Director of Strategy and Development and Director for Public Health Research at the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre at the University of Southampton; Dr Peter Norrie, Principal Lecturer in Nursing, DeMontfort University; Christopher O'Regan, Head of Health Technology Assessment and Outcomes Research, Merck Sharp and Dohme; Professor Stephen Palmer, Professor of Health Economics, Centre for Health Economics, University of York; Dr Sanjeev Patel, Consultant Physician and Senior Lecturer in Rheumatology, St Helier University Hospital; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Danielle Preedy, Lay Member; Dr John Rodriguez, Assistant Director of

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline updates previous versions: National Institute for Health and Clinical Excellence (NICE). Cardiac resynchronisation therapy for the treatment of heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 28 p. (Technology appraisal guidance; no. 120).

National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan 1. 33 p. (Technology Appraisal; no. 95).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120). Clinical audit tool. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun. Various p. (Technology appraisal guidance; no. 314). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120). Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun. 1 p. (Technology appraisal guidance; no. 314). Electronic copies: Available from the NICE Web site .
- Colquitt JI, Mendes D, Clegg AJ, Harris P, Cooper K, Picot J, Bryant J. Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure: systematic review and economic evaluation. Southampton (UK): Southampton Health Technology Assessments Centre; 2014 Jan. 664 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120). Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun. 4 p. (Technology appraisal guidance; no. 314). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide

specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on March 22, 2007. This NGC summary was updated by ECRI Institute on September 10, 2014.

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